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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,102	03/01/2002	Michael Flavin	01-128-A	4193

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EXAMINER

CALAMITA, HEATHER

ART UNIT	PAPER NUMBER
	1637

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/087,102	FLAVIN ET AL.	
	Examiner Heather G. Calamita, Ph.D.	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 01 March 2002.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1-20 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) 14 and 35 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 01 March 2002 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 14 is objected to because of the following informalities: In line 14 of the claim "for" should read from. Claim 35 is objected to because of the following informalities: In line one of the claim "for the at" the should be removed. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 recites the limitation "first frit and second frit" in line 3. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amstrong (USPN 5,422,004 06/06/1995) in view of Agrafiotis et al. (USPN 5,684,711 11/04/1997).

Amstrong teaches to identify physical variables that affect chiral selectivity for the separation of racemic mixtures, one being stationary phases. He teaches to determine a range of values of the physical variables. He teaches a finite number of experimental tests. He teaches a plurality of stationary phases and a plurality of collection tubes. He teaches assigning the test stationary phase to a particular well,

dispensing the racemic mixture solution into each of the stationary phases at a predetermined concentration, allowing the racemic mixture to pass through each stationary phase and collecting the solution in its corresponding tube. With regard to claim 5, he teaches determining an optimal racemic solution, having the highest selective adsorption, where the stationary phases are classified based on characteristics, and parameters for future experiments include stationary phases with the same characteristics as the stationary phase used for the optimal racemic solution (see whole document, specifically, examples 28 and 29, col. 29-32). With regard to claim 6, he teaches physical variables selected from the group of stationary phases, amount of stationary phase, racemic mixture solution concentration, and operating conditions (see tables 6-7). With regard to claims 7 and 18, he teaches physical variables as choice of solvents (see col. 14 lines 35-38). With regard to claim 8, he teaches physical variables as solvent percentages (see col. 14 lines 35-38). With regard to claim 9, he teaches determining enantiomeric excess (see table 9). With regard to claim 12, he teaches washing the stationary phase and re-using the phase for the next experiment (see col. 7 line 56). With regard to claim 13, he teaches assigning a stationary phase based on the parameters to a particular well, packing the test phase into the well, dispensing the racemic mixture into the different stationary phases, collecting the solution after it passes over the stationary phase and analyzing the solutions collected (see col. 16 table 9). With regard to claim 15, he further teaches analyzing to determine the magnitude of chiral resolution by determining optical rotation of the collected solution (see col. 21 lines 65-67, col. 22 lines 20-48). With regard to claim 16, he teaches a polarimeter as an analyzer (see col. 21 lines 65-67, col. 22 lines 20-48). With regard to claim 17, he teaches a chiral HPLC as an analyzer (see col. 23 line 6). With regard to claim 19, he teaches a choice of stationary phases (see col. 30 lines 52-64). With regard to claim 20 he teaches choosing a test stationary phase from a library of potential stationary phases, a finite number of experimental tests, which have the test stationary phases chosen. He teaches providing a plurality of stationary phases and a plurality of collection plates, passing the racemic solution through the stationary

phases, collecting the solutions and analyzing the contents to determine the magnitude of the chiral resolution for the solution (see examples 28 and 29, col. 29-32).

With regard to claims 1, 14, 20, Armstrong does not teach automatically generating suggested parameters for future experiments using a computer, wherein the parameters are chosen from a new range of values based on the analysis of the plurality of racemic solutions collected. With regard to claim 2, he does not teach generating a statistical analysis based on the analysis of the plurality of racemic solutions collected, wherein generating suggested parameters for future experiments is based on the statistical analysis. With regard to claim 3, he does not teach generating the statistical analysis using the computer. With regard to claim 4, he does not teach generating statistical analysis includes determining an optimal racemic solution having the highest selective adsorption. With regard to claim 10, he does not teach washing the stationary phase is automated.

Agrafiotis et al. do teach automatically generating suggested parameters for future experiments using a computer, wherein the parameters are chosen from a new range of values based on the analysis of the plurality of solutions collected (see whole document, specifically Figs. 2-3). With regard to claim 2, they teach generating a statistical analysis based on the analysis of the plurality of solutions collected, wherein generating suggested parameters for future experiments is based on the statistical analysis (see Figs. 2-3). With regard to claim 3, they teach generating the statistical analysis using the computer (see Figs. 2-3). With regard to claim 4, they teach generating statistical analysis includes determining an optimal solution having the highest selective adsorption (see Figs. 2-3). With regard to claim 10, they teach automating experimental steps (see Figs. 2-3).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Agrafiotis's method of automation with Armstrong's method for comparing chiral stationary phases in order to evaluate a greater number of stationary phases more efficiently. Agrafiotis et al. state that an automated system provides more efficient evaluation of a plurality of structure-activity models in parallel.

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(col. 4 lines 11-13). It would have been prima facie obvious to apply Agrafiotis's automation to Armstrongs's method for evaluating chiral stationary phases to achieve the expected advantage of greater efficiency in evaluating large numbers of chiral stationary phases in parallel.

*Summary*

5. No claims were allowed.

*Conclusion*

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita, Ph.D. whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday thru Thursday 7:00 A.M. - 5:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571.272.0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

hgc

JEFFREY FREDMAN  
PRIMARY EXAMINER

*[Handwritten signature]*